JUN 2 8 2000

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K001679.

1.	**Submitter name, address, contact**	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (716) 453-4041 Contact Person: Marlene A. Shulman
2.	**Preparation date**	Date Special 510(k) prepared: 31 May 2000
3.	**Device name**	Trade or Proprietary Name: VITROS Chemistry Products AST Slides VITROS Chemistry Products Calibrator Kit 3 Common Name : AST test Classification Name: Aspartate aminotransferase test system (21 CFR 862.1100).
4.	**Predicate device**	The VITROS Chemistry Products AST Slides (modified) and VITROS Chemistry Products Calibrator Kit 3 are substantially equivalent to the VITROS Chemistry Products AST Slides (current slide) and VITROS Chemistry Products Calibrator Kit 3.

Continued on next page

5. Device description

The VITROS Chemistry System uses *Vitros* Slides to perform discrete chemistry tests on body fluid specimens. All reactions necessary for a single quantitative measurement take place within the multi-layered analytical element of a *Vitros* Slide.

The system is comprised of two main elements:

1. The VITROS Chemistry Products range of chemistry products (in this case VITROS Chemistry Products AST Slides, VITROS Chemistry Products Calibrator Kit 3, which are combined by the VITROS Chemistry System to perform the VITROS AST test.

2. The VITROS Chemistry System – instrumentation, which provides automated use of the chemistry slides. Multiple VITROS Chemistry Systems were cleared for market by separate 510(k) pre-market notifications (K890928, K890929, K922072, K946090 and K922072).

Common reagent used by the VITROS System. The VITROS Chemistry Products 7% BSA was cleared by a previous 510(k) pre-market notification (K903071).

The VITROS Chemistry System and Calibrators are dedicated specifically for use only with the VITROS Chemistry Products range of products.

6. Device intended use

VITROS AST Slides
For in vitro diagnostic use only.
VITROS AST Slides quantitatively measure aspartate aminotransferase (AST) concentration in serum and plasma.

VITROS Calibrator Kit 3
For in vitro diagnostic use only.
VITROS Calibrator Kit 3 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of AcP, ALKP, ALT, AMYL, AST, CK, GGT, LDH, and LIPA.

Continued on next page

7. Comparison to predicate device

The VITROS Chemistry Products AST Slide (modified) and VITROS Chemistry Products Calibrator Kit 3 are substantially equivalent to VITROS Chemistry Products AST Slide for use with human serum and plasma which was cleared by the FDA (K934413, April 25, 1994) for in vitro diagnostic use.

Table 1 lists the characteristics of the tests performed using the VITROS AST Slide (modified) and the VITROS AST Slide(current).

Table 1 List of Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS AST Slide (Modified)	Predicate Device VITROS AST Slide (Current)
Sample volume	7 µL	11 µL
Quantity of Reactive Ingredients per slide (test)	Sodium aspartate 242 µg; sodium α-ketoglutarate 115µg ; sodium pyridoxal-5-phosphate 10 µg; sodium phosphate 38 µg; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 27µg; pyruvate oxidase(aerococcus virdans, E.C.4.1.1.3) 0.18 U; peroxidase (horseradish root, E.C.1.11.1.7) 0.45 U; and oxaloacetate decarboxylase (pseudomonas sp., E.C.1.10.3.3) 0.27 U.	Sodium aspartate 480µg ; sodium α-ketoglutarate 230µg; sodium pyridoxal-5-phosphate 20 µg; sodium phosphate 76 µg; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 54 µg; pyruvate oxidase (aerococcus virdans, E.C.4.1.1.3) 0.25 U; peroxidase (horseradish root, E.C.1.11.1.7) 0.63 U; and oxaloacetate decarboxylase (pseudomonas sp., E.C.1.10.3.3) 0.38 U.
Concentrations of Slide Reactive Ingredients per cm-squared	No Change.	Sodium aspartate 270 µg; sodium α-ketoglutarate 130 µg; sodium pyridoxal-5-phosphate 11µg; sodium phosphate 42 µg; 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 30µg; pyruvate oxidase(aerococcus virdans, E.C.4.1.1.3) 0.20 U; peroxidase (horseradish root, E.C.1.11.1.7) 0.50 U; and oxaloacetate decarboxylase (pseudomonas sp., E.C.1.10.3.3) 0.30 U.
Intended Use	No change.	For in vitro diagnostic use only. VITROS AST Slides quantitatively measure aspartate aminotransferase (AST) concentration in serum and plasma.
Basic principle	No Change.	Dry, multilayered slide utilizing reflectance spectrophotometry
Sample type	No Change.	Serum , plasma
Assay Range Serum, Plasma	No Change.	3.0- 750.0 U/L
Instrumentation	No Change.	VITROS 250, 500, 750 and 950 Series Analyzers
Incubation time and temperature	No Change.	5 minutes at 37°C

Continued on next page

8. Conclusions The information presented in the pre-market notification demonstrate that the performance of the VITROS AST Slides (modified) for use with human serum and plasma is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured aspartate aminotransferase values spanning the assay range.

The information presented in the premarket notification provide a reasonable assurance that the VITROS AST Slides (modified) for use with human serum and plasma is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 8 2000

Ms. Marlene A. Shulman
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
Regulatory Affairs MC00882
100 Indigo Creek Drive
Rochester, New York 14626

Re: K001679
Trade Name: VITROS Chemistry Products AST Slides
VITROS Chemistry Products Calibrator Kit 3
Regulatory Class: II
Product Code: CIT, CIS, CIQ, CIF
Dated: May 31, 2000
Received: June 1, 2000

Dear Mr. Shulman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K001679

Device Name:

VITROS Chemistry Products AST Slides
VITROS Chemistry Products Calibrator Kit 3

Intended Use:

VITROS Chemistry Products AST Slides
For in vitro diagnostic use only.
VITROS AST Slides quantitatively measure aspartate aminotransferase (AST) concentration in serum and plasma.

VITROS Calibrator Kit 3
For in vitro diagnostic use only.
VITROS Calibrator Kit 3 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of AcP, ALKP, ALT, AMYL, AST, CK, GGT, LDH, and LIPA.

Summary and Explanation of Test:

Aspartate aminotransferase is present in high activity in heart, skeletal muscle, and liver. Increased serum AST activity commonly follows myocardial infarction, pulmonary emboli, skeletal muscle trauma, alcoholic cirrhosis, viral hepatitis, and drug-induced hepatitis.[1]

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001679

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)